



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,969	01/27/2000	Emily L. Brooks		1609

7590

07/29/2003

THOMAS P. MCCrackEN  
POWDERJECT PHARMACEUTICAL PIC  
FLOREY HOUSE, OXFORD SCIENCE PARK  
OXFORD, OX4 4GA  
UNITED KINGDOM

EXAMINER

HAN, MARK K

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/492,969

Applicant(s)

BROOKS ET AL.

Examiner

Mark K Han

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13. 6) ☐ Other:

Art Unit: 3763

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 July 2003 has been entered.

### *Information Disclosure Statement*

2. The Examiner acknowledges the submission of an Information Disclosure Statement on 08 July 2003. U.S. Patent No. 5,630,796 to Bellhouse et al. and U.S. Patent No. 6,004,286 to Bellhouse et al. will not be considered by the Examiner because the Examiner has already cited those references in Paper No. 5. This will avoid confusion in the event the application goes to issue.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3763

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 6 and 10-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,328,714 to Bellhouse et al. (hereinafter "Bellhouse '714") in view of U.S. Patent No. 5,630,796 to Bellhouse et al. (hereinafter "Bellhouse '796"). Claim 1 of Bellhouse '714 claims a replaceable cartridge for use in a needleless syringe but fails to claim a needleless syringe and a nozzle. Bellhouse '796 shows a needleless syringe having replaceable, particle acceleration nozzle 26 with a convergent upstream end 35 and a divergent downstream end 37 including a throat 36 connecting the convergent and divergent sections. See Figures 1-3 and col. 12, lines 44-64. The upper portion (with external threads) of the nozzle is wider than the rest of the nozzle, forming a projecting annular flange, which provides an external shoulder. See Figure 1 below. The cylindrical filter medium 39 surrounds the nozzle and rests upon the external shoulder. See col. 9, lines 9-25 and col. 13, lines 20-34. This nozzle is used with a replaceable gas cartridge 11 as disclosed in Figure 4 and col. 13, lines 49-67. It would have been obvious to one of ordinary skill in the art to include the needleless syringe (to provide a means of activating the cartridge) and a nozzle (to accelerate the particles), as suggested by Bellhouse '796, with the device as claimed in Claim 1 of Bellhouse '714.

Art Unit: 3763

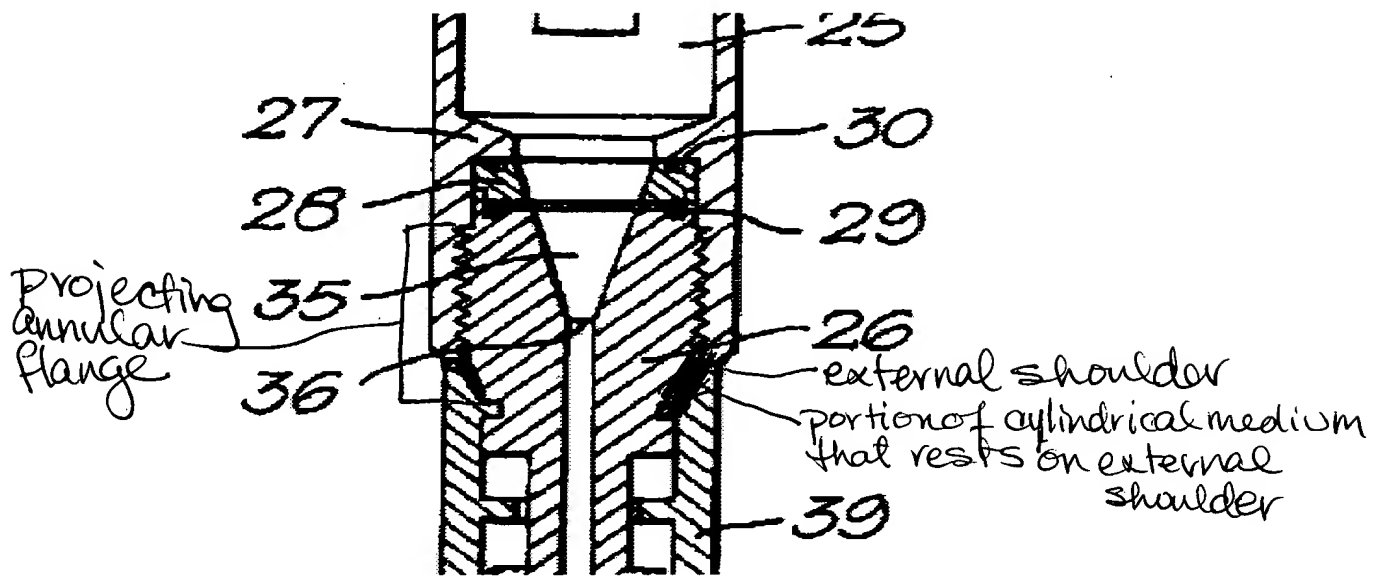


Figure 1: Portion of needleless syringe, scanned from Figure 1 of U.S. Patent No. 5,630,796 to Bellhouse et al.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellhouse '796.

Bellhouse '796 shows a needleless syringe having replaceable, particle acceleration nozzle 26 with a convergent upstream end 35 and a divergent downstream end 37 including a throat 36 connecting the convergent and divergent sections. See Figures 1-3 and col. 12, lines 44-64. The upper portion (with external threads) of the nozzle is wider than the rest of the nozzle, forming a projecting annular flange, which provides an external shoulder. See Figure 1

Art Unit: 3763

above. The cylindrical filter medium 39 surrounds the nozzle and rests upon the external shoulder. See col. 9, lines 9-25 and col. 13, lines 20-34. This nozzle is used with a replaceable gas cartridge 11 as disclosed in Figure 4 and col. 13, lines 49-67.

*Response to Arguments*

5. Applicant's arguments filed 08 July 2003 have been fully considered but they are not persuasive. It is the examiner's position that the spacer/cylindrical filter medium 39 actually rests upon the outwardly projecting flange of the nozzle 26 as shown above. The most proximal inwardly projecting flange 40 actually engages the nozzle. The other inwardly projecting flanges cooperate with the outwardly extending flanges 41 to provide a tortuous path for the shockwave resulting from the injection. The obviousness-type double patenting rejection and the rejection under 35 U.S.C. 102(b) stands.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K Han whose telephone number is 703-308-4543. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Art Unit: 3763

*mbh.*

Mark Han  
Patent Examiner  
Art Unit 3763

mkh  
July 27, 2003

*Michael J. Hayes*

MICHAEL J. HAYES  
PRIMARY EXAMINER